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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/041,911	01/07/2002	Frank E. Manning	GUID.038US01	4087
51294	7590	11/29/2006	EXAMINER	
HOLLINGSWORTH & FUNK, LLC 8009 34TH AVE S. SUITE 125 MINNEAPOLIS, MN 55425			FOREMAN, JONATHAN M	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 11/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/041,911

Applicant(s)

MANNING ET AL.

Examiner

Jonathan ML Foreman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 24-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 11-15, 24-37 and 40-54 is/are rejected.
- 7) ☒ Claim(s) 9, 10, 38 and 39 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 2, 8, 15, 24 – 31, 37 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,638,268 to Niazi in view of U.S. Patent No. 4,586,923 to Gould et al. and U.S. Patent No. 6,408,214 to Williams et al.

In regards to claims 1, 2, 8, 15, 24 – 31, 37 and 42, Niazi a guide catheter including an outer sheath (11) having an open lumen and a pre-shaped distal end (Col. 4, lines 4 – 31); an inner sheath (12) having an open lumen configured to receive a payload, the inner sheath disposed within the open lumen of the outer sheath, the inner sheath being axially rotatably and longitudinally translatable relative to the outer sheath (Col. 3, lines 12 – 15), a distal end of the inner sheath conforming to a shape of the outer sheath when the inner sheath is retracted, and the distal end of the inner sheath assuming a pre-formed shape when the distal end of the inner sheath is extended beyond the distal end of the outer sheath (Col. 3, lines 10 – 23; Col. 4, lines 4 – 8); a steering tendon along the outer sheath, a distal end of the tendon connected to a distal tip of the outer sheath (Col. 3, lines 55 - 61); a guide handle (28) connected to a proximal end of the outer sheath; and a steering mechanism comprising a torque screw (29) pivotably connected to the handle, the steering mechanism connected to a proximal end of the tendon and providing a pulling force on the steering tendon in response to pivoting of the steering mechanism to adjust a shape of the preshaped distal

end of the outer sheath (Col. 3, line 61 – Col. 4, line 3). However, Niazi fails to disclose the steering mechanism comprising a lever. Gould et al. discloses a steerable catheter having a steering mechanism including either a pivoting torque screw (120) or pivoting lever (102). It would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the pivotably connected torque screw as disclosed by Niazi with a pivotably connected lever as taught by Gould et al. in that Gould et al. teaches a torque screw and lever as being functionally equivalent and therefore interchangeable (Col. 8, lines 25 – 27). Niazi discloses an occlusion device (21) connected to the distal end of the outer sheath (Col. 3, lines 43 – 46). Niazi discloses the outer sheath having a second lumen, the steering tendon disposed within the second lumen of the outer sheath (Col. 3, lines 55 – 59). Niazi discloses the payload comprising a pacing lead configured for implantation with a coronary sinus or branch vessel (Col. 3, lines 29 – 31). Niazi discloses the payload comprising a guide wire and a lead having a lumen dimensioned to receive the guide wire (Col. 5, lines 57 – 64). The open lumen disclosed by Niazi is capable of receiving a payload comprising an injectable media (Col. 4, lines 56 – 58). Niazi discloses the distal end of the inner sheath assuming a pre-formed shape when the distal end of the inner sheath is extended beyond the distal end of the outer sheath (Col. 3, lines 10 – 23; Col. 4, lines 4 – 8), but fails to disclose the pre-formed shape being different from the shape of the outer sheath. However, Williams et al. discloses a guide catheter wherein the distal end (14) of the inner sheath (10) assumes a pre-formed shape different from the shape of the outer sheath when the distal end of the inner sheath is extended beyond the distal end of the outer sheath (Col. 4, lines 39 – 56). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the inner sheath as disclosed by Niazi to assume a pre-formed shape different from the shape of the outer sheath when the distal end of the inner sheath is extended beyond the distal end of the outer sheath in order to

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allow for a substantial number of two and three-dimensional curvatures to assist in navigating the catheter through the patient's vasculature (Col. 4, lines 56 – 64).

3. Claims 3, 4, 32, 33, 46 – 48 and 52 - 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,638,268 to Niazi in view of U.S. Patent No. 4,586,923 to Gould et al. and U.S. Patent No. 6,408,214 to Williams et al. as applied to claims 1 and 24 above, and further in view of U.S. Patent No. 5,409,469 to Schaerf.

In regards to claims 3, 4, 32, 33, 46 – 48 and 52 - 54, Niazi in view of Gould et al. and Williams et al. fails to disclose a longitudinally disposed pre-stress line extending from the proximal end to the distal end of the outer or inner sheath, or the guide handle comprising separation grips and at least one longitudinally disposed pre-stress line to facilitate separation of the guide handle in at least two sections. However, Schaerf discloses a lead introducer having a longitudinally disposed pre-stress line (63) extending from the proximal end to the distal end (Col. 5, lines 25 – 45). Schaerf discloses the guide handle comprising separation grips (Col. 5, lines 30 – 32) and at least one longitudinally disposed pre-stress line (63) to facilitate separation of the guide handle in at least two sections. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as disclosed by Niazi in view of Gould et al. and Williams et al. to include pre-stress lines and separation grips as taught by Schaerf to aid in the removal of the sheath without requiring the sheath to be removed from an end of the lead (Col. 5, lines 25 – 29).

4. Claims 5, 6, 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,638,268 to Niazi in view of U.S. Patent No. 4,586,923 to Gould et al. and U.S. Patent No. 6,408,214 to Williams et al. as applied to claims 1 and 24 above, and further in view of U.S. Patent Application Publication No. 2001/0039413 to Bowe.

In reference to claims 5, 6, 34 and 35, Niazi in view of Gould et al. and Williams et al. fails to disclose at least one electrode on the distal end of the inner or outer sheath, and an electrical conductor being coupled to the electrode and being disposed within the inner or outer sheath. However, Bowe discloses a guide catheter having at least one electrode on the distal end of the inner sheath and at least one electrical conductor coupled to the at least one electrode, the conductor being disposed within the inner sheath [0046]. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as disclosed by Niazi in view of Gould et al. and Williams et al. to include at least one electrode as taught by Bowe in order to provide energy to the tissue to treat different ailments of the heart. Furthermore, it would have been an obvious engineering design choice to place the electrode as disclosed by Bowe on the outer sheath in that the electrode would perform the same function being placed on the outer sheath as well as the inner sheath.

5. Claims 7 and 36, are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,638,268 to Niazi in view of U.S. Patent No. 4,586,923 to Gould et al. and U.S. Patent No. 6,408,214 to Williams et al. as applied to claims 1 and 24 above, and further in view of U.S. Patent No. 6,533,770 to Lepulu et al.

In reference to claims 7 and 36, Niazi in view of Gould et al. and Williams et al. discloses an occlusion device being connected to the pre-shaped distal end of the outer sheath (Col. 3, lines 43 – 46). However, Niazi in view of Gould et al. and Williams et al. fails to disclose an occlusion device being connected to the inner sheath and at least one pressure sensing device connected to the inner or outer sheath. However, Lepulu et al. discloses a guiding member having an occlusion device connected to the distal end of the inner sheath and a pressure sensing device located within the inner sheath (Col. 17, lines 26 – 35). It would have been obvious to one having ordinary skill in the

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art at the time the invention was made to modify the device as disclosed by Niazi in view of Gould et al. and Williams et al. to include an occlusion device and a pressure sensing device as taught by Lepulu et al. in order to further the diagnostic capabilities of the device.

6. Claims 11 – 14, 40 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,638,268 to Niazi in view of U.S. Patent No. 4,586,923 to Gould et al. and U.S. Patent No. 6,408,214 to Williams et al. as applied to claims 1 and 24 above.

In regards to claims 11, 12 and 40, Niazi in view of Gould et al. and Williams et al. discloses the outer sheath having a substantially circular curve proximally adjacent to a strait section, the curve having a bend radius ranging from about 0 degrees to about 180 degrees and a bend radius from about 1 cm to 7 cm. Niazi in view of Gould et al. and Williams et al. discloses the inner sheath having a substantially circular curve proximally adjacent to a strait section, the curve having a bend radius ranging from about 0 degrees to about 150 degrees and a bend radius from about 1 cm to 5 cm (Col. 4, lines 4 – 23). However, Niazi in view of Gould et al. and Williams et al. fails to disclose the tip of the outer sheath having a length of about 1 cm to 5 cm and the tip of the inner sheath having a length of about 0.5 cm to about 4.0 cm. Niazi in view of Gould et al. and Williams et al. teaches that the predetermined shape and size of the curve can be changed to accommodate different heart sizes (Col. 4, lines 25 – 31). It would have been obvious to modify the size and shape of the predetermined curves as needed to accommodate different heart sizes as taught by Niazi in view of Gould et al. and Williams et al..

In reference to claims 13, 14 and 41, Niazi in view of Gould et al. and Williams et al. discloses the tendon being disposed along the outer sheath (Col. 3, lines 55 – 59), but fails to disclose the tendon being on outer surface of the sheath or within the open lumen of the sheath. However, due to the lack of criticality in the specification for the positioning of the steering tendon,

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it would have been obvious to one having ordinary skill in the art at the time the device was made to position the tendon on the surface or within the interior of the lumen as desired.

7. Claims 43- 45 and 49 - 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,638,268 to Niazi in view of U.S. Patent No. 4,586,923 to Gould et al. and U.S. Patent No. 6,408,214 to Williams et al. as applied to claims 1 and 24 above, and further in view of U.S. Patent No. 5,462,527 to Stevens-Wright et al..

In regards to claims 43 – 45 and 49 – 51, Niazi in view of Gould et al. and Williams et al. disclose a guide catheter including wherein the lever (102) of the steering mechanism comprises a steering handle (104), but fail to disclose the steering handle including a retention mechanism configured to retain the steering handle at a fixed position. However, Stevens-Wright et al. discloses a guide catheter including a steering handle comprising a retention mechanism configured to frictionally lock a steering mechanism at a fixed position (Col. 9, lines 27 – 34). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the steering handle as disclosed by Niazi in view of Gould et al. and Williams et al. to include a retention mechanism as taught by Stevens-Wright et al. in order to maintain a particular bend in the guide catheter (Col. 9, lines 30 – 34).

Response to Arguments

8. Applicant's arguments filed 9/18/06 have been fully considered but they are not persuasive. Applicant asserts that the inner sheath as disclosed by Niazi is not axially rotatable relative to the outer sheath. However, the Examiner disagrees. The inner sheath is capable of sliding in and out of the outer sheath (Col. 3, lines 12 – 13). The inner sheath is also more pliable than the outer sheath (Col. 3, lines 14 – 15). Because the inner sheath is capable of being drawn into the outer sheath, the inner sheath is more pliable than the outer sheath, and no structure limits or hinders rotation of the

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inner sheath, the inner sheath is at least partially rotatable within the outer sheath. Applicant asserts that the Examiner is impermissibly taking official notice that a torque screw and lever are functionally equivalent and therefore interchangeable. However, the Examiner has not taken official notice but has properly relied on the teaching of Gould et al. In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents. In re Ruff, 256 F.2d 590, 118 USPQ 340 (CCPA 1958). See MPEP 2144.06. In this case, Gould et al. teaches the equivalency of the torque screw and the lever. Additionally, Applicant asserts that a skilled artisan would not have looked to Gould et al. to modify Niazi because Gould et al. does not teach an open lumen, telescopic inner or outer catheters, or a pre-formed shape of a flexible end. However, the Examiner disagrees. As with Niazi, Gould et al. is directed to manipulating a catheter through tortuous body lumens to arrive at a desired location. One having ordinary skill in the art would see that modifying the pre-formed shape of the inner sheath as disclosed by Niazi to include a shape different from the shape of the outer sheath when the distal end of the inner sheath is extended beyond the distal end of the outer sheath as taught by Williams et al. allows for a substantial number of two and three-dimensional curvatures to assist in navigating the catheter through the patient's vasculature in regions other than that as intended by Niazi.

Allowable Subject Matter

9. Claims 9, 10, 38 and 39 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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